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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/507,525
Filing Date: September 14, 2004
Appellant(s): OBEREGGER ET AL.

Robin L. Teskin
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/05/06 appealing from the Office action mailed 07/14/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2003/0161874

Li et al.

08-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 155-172 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties recited in the claims. It appears from the specification that the claimed functional properties are achieved from specific formulations that contain specific structures, such as dosage core with coating layers that comprise specific ratios of film forming polymers (pages 18-19 and 21; examples 1 and 2). This is also evident by the comparison data showing formulations with different structure that resulted in different functional properties (see comparative example 8). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the structure which makes up the formulation must be clearly and positively specified in order to place one of skill in the art in possession of the claimed tablets with the desired properties. It is precisely this structure that determines the desired properties and without which, one could not replicate the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1615

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 155-172 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 155-172 contain the trademark/trade name Wellbutrin® and/or Zyban/Wellbutrin® SR. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe bupropion and, accordingly, the identification/description is indefinite. There is no description in the specification of the exact ingredients of Welbutrin® and Zyban/Wellbutrin®, which can change over time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 155, 156, 159-162, 165-167 and 169-171 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. US 2003/0161874.

Li discloses a sustained release formulation in a form of tablet or capsule comprising bupropion hydrochloride for once a day administration (abstract; paragraphs 0021, 0024 and 0075). The amount of bupropion is 75-450 mg (paragraph 0028). The formulation is useful for the treatment of depression (paragraph 0022). Li further discloses a C_{max} for bupropion at about 8 hours (T_{max}) is 54.2 ng, and AUC_{0-inf} is 832 ng.hr/ml (table 3).

It is noted that Li does not explicitly teach the formulation that does not exhibit any food effects. However, it is the examiner's position that this limitation is inherent because Li teaches a formulation that has the same C_{max} and AUC values.

(10) Response to Argument

Appellant argues that the use of the trade name "Welbutrin[®]" or "Zyban/Wellbutrin[®] SR" in the claims is proper because: 1) the specification provides Tables as well as Figures which are referred to in the examples that contain the AUC_{inf} , AUC_{0-t} and C_{max} parameters (PK parameter); and 2) "Welbutrin[®]" or

“Zyban/Wellbutrin® SR” formulations were approved by the FDA for usage in treating depression or smoking cessation cannot be changed without the manufacturer thereof obtaining the FDA’s express approval due to public safety and efficacy issues.

However, in response to the appellant’s arguments, first, it is noted that the Tables and examples referred to by the appellant described only the AUC inf, AUC 0-t and PK parameter for specific dosage forms in one particular designed study. The specification does not set forth under what condition, all the parameters intended to be met. So as define what the instant formulation is to be compared to. Nowhere does the specification provide the exact ingredients of Welbutrin® and Zyban/Wellbutrin® SR formulations. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. *Ex Parte Kattwinkle*, 12 USPQ 11 (Bd. App. 1931). Indeed, appellant states on page 11, 3rd paragraph of the appeal brief that the claimed composition is to be identified by comparison of the bioequivalence to the pharmacokinetic parameters, not the structural constituents of the specifically referenced drugs, making it impossible to determine the structures encompassed by the claim. Second, the relationship between a trademark and the product it identifies is indefinite, uncertain, and arbitrary, because the formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. Applicant’s statement that the Wellbutrin® and Zyban®/Wellbutrin® SR formulations “cannot be changed without the manufacturer thereof obtaining the FDA’s express approval” implied that the Wellbutrin® and Zyban/Welbutrin® SR formulations

can be changed with the approval of the FDA. Accordingly, the use of the trademark/trade name Welbutrin® and/or Zyban/Welbutrin® SR in the claims is improper.

Appellant argues that the written description rejection under 112, first paragraph is improper because:

1) the present specification establishes that they were in possession of the claimed invention as defined by the recited structural and functional features and moreover would place the ordinary skilled artisan in possession of modified release tablet according to the claims.

However, evidence of a single species of embodiment is commercially successful is not correlative with possession of the full scope of claimed tablets, which have no structural core, drug or coating parameters and yet requiring particular functions. Specification discloses several structures that result in several different functional features (see for example table 7). Table 7 shows that different formulations containing different structures will result in different release rates. The release rates for formulations A, B, C stop at about 17 hours, while the release rates of formulations A', B', C' continue to at least 24 hours. The specification fails to describe to one of ordinary skill in the art if any "modified-release tablet" would result in the specific bioequivalent given the broad recitation in the claims. Independent claim 155 does not even require any coating, any sustained/modified release polymer. Claim 157 recites a moisture barrier, however, the specification discloses the moisture barrier is not an enteric coating barrier, and therefore, does not regulate/control the release rate of the drug. See for example page 34 of the specification, lines 1-2, "cores are subsequently coated

Art Unit: 1615

with a moisture barrier, which substantially impede or retards absorption of moisture”.

The appellant, the claims and the specification are contradicting in the sense that the appellant alleges that the claimed bioequivalent is achieved from a tablet with a moisture barrier, while the specification discloses that the moisture barrier does not control the release of the drug. Accordingly, one of ordinary skill in the art when reading claim 157 in to claim 155 in view of the description in the specification would not be able to obtain a formulation having the specific bioequivalent.

2) the genus of modified release tablets claimed have well defined, readily variable structural and functional features.

However, although the claims are interpreted in light of the specification, the disclosures of the structural and functional features in the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993) (Claims to a superconducting magnet which generates a “uniform magnetic field” were not limited to the degree of magnetic field uniformity required for Nuclear Magnetic Resonance (NMR) imaging. Although the specification disclosed that the claimed magnet may be used in an NMR apparatus, the claims were not so limited.).

Furthermore, the claimed bioequivalent can be achieved only from formulations that contain specific structures, including specific ingredients and amounts used in the core and in the coating (pages 18-19 and 21; examples 1 and 2). This is also pointed out by the appellant. On page 24 of the Appeal Brief, appellant conceded that “the subject specification only exemplified 2 bioequivalent bupropion tablet formulation” comprise of specific polymeric constituent and percentages. Furthermore, the present specification

clearly states even the closest prior art, Seth '327, teaches formulations using the same materials but different ratios of ingredients, result in different bioequivalent than the claimed bioequivalent (see comparative example 8). During the personal interview dated 05/31/06, Appellant also admitted the claimed bioequivalent can be achieved in formulations having specific ratios of the water-insoluble water permeable film forming polymer to plasticizer to water-soluble polymer (see originally filed claims 45 and 47 in Appendix A). Accordingly, the written description rejection is proper because one skilled in the art would not be able to obtain the claimed bioequivalent from reading claim 155. Claim 168 recites the controlled release coating, but lack the ratios that result in the claimed functions.

3) the specification provides descriptive support for the contemplated breadth of invention.

However, it is noted that the current rejection under 35 U.S.C. 112, first paragraph is not based on lack of literal descriptive support for the language used to claim the invention, it is based on lack of possession of the full scope of the genus control-release tablets encompassed by the claims based on the limited disclosure of 2 species of control-release tablets. As discussed above in item number 2, the 2 species showed in the specification with different parameters result in different properties. The specification at pages 17-18 discloses water-insoluble polymer for the coating includes cellulose ester, cellulose ether, and polyvinyl alcohol. Cellulose ester and cellulose ether comprise a large number of polymers that can be used as a controlled release coating, for example hydroxypropylmethylcellulose, hydroxypropylcellulose, or

propylcellulose. Polyvinyl alcohol is a different class of water-insoluble polymer, which has different properties over the release rate of a drug. However, the specification described only ethylcellulose as a water-insoluble polymer in formulation that results in the claimed bioequivalent. The specification lacks the description which representative of the full scope encompassed by the claims.

4) the appellant should not be limited to the specific embodiments that are reduced to practice.

However, the criticality of the specific coating and polymer ratios to achievement of the required specific functional properties is evidenced not only by the specification at page 28 (table 3), but also by appellant at page 19 of the brief, where it is argued that the prior art structures do not meet the functional limitations of the claim because they differ in polymer ratios. This would indicate that the specific polymer structures are vital to the functioning of the claimed controlled release tablet, and are a required limitation in order to place one of ordinary skill in the art in possession of the claimed tablet. To be more specific, at page 24 of the brief, appellant concedes that "the subject specification only exemplifies 2 bioequivalent bupropion tablet formulations that respectively contain 150 or 300 mg of bupropion, and which each further respectively comprise (i) a control-release coating that substantially controls bupropion drug release as well as (ii) a moisture barrier coating that impedes moisture retention, wherein both coating s are comprised of specific polymeric constituents comprised in specific weight percentages." As discussed above in item number 3, the specification discloses a number of different classes of polymers. Each of which possesses different properties,

Art Unit: 1615

and therefore, effects the release profiles in various way. In another word, if polyvinyl alcohol for example, was used as a water-insoluble in the control-release coating in the amount as discloses in table 3, can the same release profiles and the same bioequivalent be achieved? Further, table 3 shows a narrow ratio between the water-insoluble and water-soluble polymers in order to achieve the specific bioequivalent. Thus, without undue experiment, one of ordinary skill in the art would not have been able to achieve the claimed bioequivalent, because the present specification at pages 19-20 discloses a broader range for the ratio between the water-insoluble and water-soluble polymers.

Appellant argues that it would be apparent to a skilled artisan in possession of this application to select the desired bioequivalent properties because the present specification exemplifies a wide range of different film-forming polymers, plasticizers and water-soluble polymers that may be substituted for those contained in the exemplified control-release coatings.

However, one of ordinary skill in the art would have to go through undue experimentation to determine/select the desired bioequivalent. As noted by appellant at page 26, the specification exemplifies a *wide range* of different film-forming polymers, plasticizers and water-soluble polymers, one of ordinary skill in the art in order to achieve the claimed bioequivalent would have to: 1) experiment all the film-forming polymers from the *wide range* of water-insoluble polymers; 2) experiment all the plasticizers; 3) experiment all the water-soluble polymers from the wide range list; and 4) modify the ratios between these three components from the wide range of ratios.

Appellant argues that the genus of modified-release tablets claimed have well defined, readily verifiable structural and functional features.

However, it is noted that the required structure to result in the claimed functional features is not in the claims, e.g., no structural core, drug or coating parameters. The description in the specification at pages 14-23 does not well define the tablet that results in the claimed particular functions. Table 7 from the present specification shows that different structures will result in different release rates. The release rates for formulations A, B, C stop at about 17 hours, while the release rates of formulations A', B', C' continue to at least 24 hours. The specification fails to describe to one of ordinary skill in the art if any "modified-release tablet" would result in the specific bioequivalent given the broad recitation in the claims. Independent claim 155 does not even require any coating, any sustained/modified release polymer. Claim 157 recites a moisture barrier, however, the specification discloses the moisture barrier is not an enteric coating barrier, and therefore, does not regulate/control the release rate of the drug. See for example page 34 of the specification, lines 1-2, "cores are subsequently coated with a moisture barrier, which substantially impede or retards absorption of moisture". The appellant, the claims and the specification are contradicting in the sense that the appellant alleges that the claimed bioequivalent is achieved from a tablet with a moisture barrier, while the specification discloses that the moisture barrier does not control the release of the drug. Accordingly, one of ordinary skill in the art when reading claim 157 in to claim 155 in view of the description in the specification would not be able

to obtain a formulation having the specific bioequivalent. Claim 168 recites the controlled release coating, but lack the ratios that result in the claimed functions.

Appellant argues "Enzo" in support of functional limitations being sufficient to describe an invention. However, it is noted that Enzo's drawn to genetic material, and the functional limitation of hybridization immediately implies a requisite structure. In contrast to Enzo, the instant functional limitations do not immediately imply and requisite the tablet formulation.

Appellant's arguments regarding the 112, 1st paragraph enablement rejection are persuasive, and therefore, the rejection has been withdrawn.

Appellant argues that the 102(e) rejection is traversed because Li does not teach or suggest: 1) a once-a-day bupropion tablet formulation that is bioequivalent to Wellbutrin or Zyban/Wellbutrin[®] SR; and 2) tablet formulation that is free of any food effects.

However, it is the position of the examiner that the formulation of Li necessary exhibits the same properties being claimed, because Li discloses a formulation having the same structural elements required by the claims that results in the claimed properties, such as a C_{max} for bupropion at about 8 hours (T_{max}) is 54.2 ng, and AUC_{0-inf} is 832 ng.hr/ml (table 3). Therefore, since the art meets the only structural requirements present, it must be "bioequivalent".

Further, as stated by the Appellant at page 12 of the brief, the specific properties recited in the claims, such as the AUC and C_{max} parameters are the results encompassed by bioequivalent modified release dosage form. Similarly, Li discloses

Art Unit: 1615

the same composition that has the same AUC and C_{max} , hence, the composition of Li inherently possess the same bioequivalent, because as concedes by the Appellant, the AUC and C_{am} are the parameters possessed by the bioequivalent.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S. Tran

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